

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Toth et al.	Examiner:	Schlientz, Nathan
Application No.:	10/800,291	Group Art Unit:	1616
Filed:	March 12, 2004	Docket No.:	14669.0064USU1
Title:	STABLE PHARMACEUTICAL COMPOSITIONS OF DESLORATADINE		
Confirmation No.	8286		

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (37 C.F.R. § 1.97(c))

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed, modified Form 1449 are brought to the attention of the Examiner.

Applicants' corresponding European patent (EP 1 507 531 B1, granted January 24, 2007) was opposed by Quimica Sintetica, S.A. (hereafter "Opponent"). A copy of the Opponent's arguments filed October 24, 2007 is enclosed and cited under "NON-PATENT DOCUMENTS" in the Form 1449. In the outstanding Opposition, the Opponent cited the following documents:

- 1) U.S. Patent No. 6,506,767 (**D1**);
- 2) U.S. Patent No. 4,659,716 (**D2**);
- 3) WIPO Published Application WO 92/00293 (**D3**);
- 4) An excerpt from the Opposition proceedings concerning EP 0 993 455 (**D4**);
- 5) WIPO Published Application WO 00/02560 (**D5**);
- 6) EP 0 208 855 (**D6**);
- 7) "Clinical Pharmacology and Biopharmaceutics Review" published on December 21, 2001 on the FDA website for Clarinex (tablets 5 mg desloratadine), (**D7**); and
- 8) "European Public Assessment Report (EPAR) of the EMEA of Aerious (film-coated tablets 5 mg desloratadine) (**D8**).

U.S. Patent Nos. 6,506,767 (**D1**) and 4,659,716 (**D2**) are of record in the present application. Accordingly, Applicants have cited and have attached documents **D3 – D8** for the Examiner's consideration.

As to the document "An excerpt from the Opposition proceedings concerning EP 0 993 455," Applicants note that this document was filed on December 14, 2006 by the Proprietor (Schering Corporation) of EP 0 993 455 in response to an Opposition filed by Egis Gyogyszergyar RT. Applicants also note that EP 0 993 455 corresponds to WO 99/01450, which was cited in an Information Disclosure Statement filed November 8, 2004. Additionally, Applicants note that the Opponent of EP 0 993 455 cited the following documents: WO

92/00293; WO 95/01792; and U.S. Patent No. 4,659,716. U.S. Patent No. 4,659,716 is of record, but WO 92/00293 and WO 95/01792 are not. Accordingly, Applicants cite herein WO 92/00293 and WO 95/01792.

Applicants have cited and have attached a copy of EP 1 507 531 B1 for the Examiner's convenience.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that a reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication. Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.



Respectfully submitted,
MERCHANT & GOULD P.C.
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A handwritten signature in dark ink, appearing to read "Daniel R. Evans". The signature is fluid and cursive, written over a horizontal line.

Daniel R. Evans, Ph.D.
Registration No. 55,868

Date: October 1, 2008